

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**Z.H. , by and through KEVIN
HUTCHENS and CHRISTIN
HUTCHENS, individually and as
parents and next friends of Z.H.**

Plaintiff,

Vs.

**ABBOTT LABORATORIES, INC. and
ABBVIE, INC.**

Defendant.

CASE NO.1:14CV176

JUDGE CHRISTOPHER A. BOYKO

ORDER

CHRISTOPHER A. BOYKO, J:

This matter is before the Court on Plaintiffs' Motion to Exclude Certain Opinion Testimony of Dr. David M. Yousem (ECF # 86). For the following reasons, the Court grants, in part, and denies, in part, Plaintiffs' Motion.

Dr. David Yousem is a Professor of Radiology and Director of Neuroradiology at Johns Hopkins Hospital. Defendants offer him as an expert witness in Neuroradiology and he offers the following opinions in his expert report:

- 1) The abnormalities reflected on the MRIs of Z.H.'s brain are most consistent

with a hypoxic-ischemic injury that occurred around the time of his birth;

- 2) There is no reason to suggest that Depakote caused the brain damage that is reflected on the MRI; and
- 3) The MRI findings are consistent with findings in children who were never exposed to Depakote that have suffered hypoxic-ischemic injuries that cause significant motor and cognitive impairment.

In reaching these opinions, Dr. Yousem relied on his education and twenty plus years of experience in radiology and training. Dr. Yousem reviewed Z.H.'s medical records, MRI images of Z. H. and Depakote-exposed case studies and relevant medical literature and articles concerning imaging studies in connection with fetal Depakote exposure.

Plaintiffs move to preclude Dr. Yousem from testifying that Z.H.'s brain imaging is inconsistent with Depakote exposure.¹ According to Plaintiffs, Dr. Yousem never reviewed imaging of a patient with a clinical history of Depakote exposure prior to this suit. Dr. Yousem testified he was unaware of fetal valproate syndrome prior to this suit. Although Dr. Yousem has general experience in reviewing brain imaging, he only reviewed two case reports, each involving a single patient. According to Plaintiffs, this lack of experience with

¹ The Court notes that Plaintiffs' Motion lacks consistency in what testimony they seek to be excluded. At page one of the Motion Plaintiffs write "Dr. Yousem should be prohibited from testifying on whether Z.H.'s brain imaging is inconsistent with Depakote exposure." On page 3 it reads "The Court should therefore prohibit Dr. Yousem from testifying regarding any potential neuroradiologic manifestations of Depakote exposure." Finally, in their Conclusion Plaintiffs write, the Court should "exclude Dr. Yousem's opinions regarding indications of Depakote exposure in Z.H.'s brain imaging." These requests do not accurately reflect the substance of Dr. Yousem's opinions and are not consistent regarding what Plaintiffs seek to exclude.

the brain scans of patients with Depakote exposure precludes him from offering an opinion that Z.H.'s brain injuries are not consistent with Depakote exposure.

Plaintiffs argue that the medical literature reviewed by Dr. Yousem cannot provide a basis for his opinion that Z.H.'s injuries were not caused by Depakote exposure because they only described clinical manifestations and did not contain imaging. These articles do not describe radiologic imaging related to central nervous system manifestations, only clinical manifestations. Dr. Yousem said he could "imagine" the brain images of the children in the literature who suffered from spina bifida and craniosynostosis. However, Z.H. does not suffer from spina bifida or craniosynostosis. Therefore, Plaintiffs argue the medical literature reviewed by Dr. Yousem is not relevant to his report and cannot provide a basis for his conclusion that Z.H.'s brain injuries are inconsistent with in utero Depakote exposure.

Plaintiffs contend that two case studies are insufficient under Fed. R. Evid. 702 and 703 to form the basis of Dr. Yousem's opinions. Therefore, according to Plaintiffs, he must be precluded from offering such testimony.

Defendants argue Dr. Yousem's testimony is based on his experience, education and review of available medical literature. His primary opinion testimony is that Z.H.'s MRIs reflect damage that is most consistent with hypoxic-ischemic injury to the brain (lack of oxygen and blood). Plaintiffs do not challenge this opinion. Dr. Yousem then opines that the medical literature does not evidence a causal link between Depakote and hypoxic-ischemic injury. According to Defendants, this is consistent with the fact that Depakote has been on the market for thirty years and no medical literature associates Depakote with such an injury. After reviewing the literature on the types of neurologic injuries associated with Depakote,

Dr. Yousem noted that Z.H. does not have these types of injuries.

Dr. Yousem then considered events reflected in Z.H.'s medical records evidencing oxygen and blood deprivation. Comparing Z.H.'s brain and facial scans in light of the medical record, Dr. Yousem opines that Z.H.'s injuries are consistent with hypoxic-ischemic injury. Dr. Yousem describes areas of dead tissue in Z.H.'s brain. These areas are consistent with hypoxic-ischemic injury as it is the most common cause of cell death according to Dr. Yousem. Dr. Yousem testified that "the location of the abnormality and the presence of restricted diffusion overwhelmingly suggests that this is from an hypoxic-ischemic injury." (Depo pg. 40). Dr. Yousem attests that the area of Z.H.'s brain so affected is most vulnerable when there is restriction of the blood supply. He then noted that none of the literature or scans he reviewed describe hypoxic-ischemic injury as a result of Depakote exposure in utero.

Dr. Yousem further opines that the MRI of Z.H. is consistent with those of children who were never exposed to Depakote but suffered hypoxic-ischemic injuries, resulting in significant motor and cognitive impairment.

Rule 702 of the Federal Rules of Evidence states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 703 states:

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on

the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Under Federal Rules of Evidence, a trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, (1993). The objective of *Daubert*'s "gatekeeping" function is to ensure the reliability and relevancy of expert testimony. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). The Supreme Court has held this "gatekeeping" obligation applies not only to scientific testimony, but to all expert testimony. *Id.* at 147. Courts are not required to hold a formal hearing on *Daubert* challenges. *See Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir.1999). "[N]o matter how good" experts' "credentials" may be, they are "not permitted to speculate." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671 (6th Cir. 2010) quoting *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1088 (10th Cir.2000). "The party offering expert testimony bears the burden of establishing the foundational elements of admissibility by a preponderance of proof." *Jones v. Pramstaller*, 874 F. Supp. 2d 713, 718 (W.D. Mich. 2012) citing *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir.2001). "Nevertheless, Rule 702's requirements are applied liberally, leaving '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof [as] the traditional and appropriate means of attacking shaky but admissible evidence.'" *Jones*, 874 F.Supp.2d at 718 quoting *Daubert*, 509 U.S. at 596.

Upon review of the Motion, brief and supporting materials, the Court grants Plaintiffs'

Motion to Exclude Certain Testimony of Dr. Yousem, in part. Plaintiffs do not challenge Dr. Yousem's credentials and qualifications to opine on MRI images, nor do they contest Dr. Yousem's opinion on the consistency of Z.H.'s MRI scan with those of someone who has suffered a hypoxic-ischemic event. Instead, Plaintiffs challenge Dr. Yousem's opinions that Z.H.'s brain images are inconsistent with Depakote exposure.

The Court agrees with Defendants that Dr. Yousem is qualified by education and experience to opine on what Z.H.'s MRI images reveal concerning the nature of his injuries. Dr. Yousem is a board certified radiologist with a subspecialty in neuroradiology. He has over twenty years experience as a radiologist and has written a book on neuroradiology entitled "Neuroradiology, The Requisites." He reviews one to two MRIs of newborns every week. Thus, his education and experience qualify him as an expert in neuroradiology and interpreting MRI scans. Furthermore, he has general experience viewing imaging of children having experienced hypoxic-ischemic injury. Therefore, his opinions concerning the consistency of Z.H.'s injuries with hypoxic-ischemic injury are reliable and supportable under Rule 702.

However, Dr. Yousem reviewed the scans of only two case studies of patients with Depakote exposure testifying that these were the only two case studies focused on imaging he could find in the available medical literature. Dr. Yousem has no prior experience with reviewing the imaging of Depakote-exposed patients. The Court holds that two imaging studies involving only two patients is insufficient to form the basis of Dr. Yousem's opinion that there is no reason to suggest that Depakote caused the brain damages that is reflected on Z.H.'s MRI. There simply is not an sufficient body of available imaging studies to support

such a conclusion, thus rendering it scientifically unreliable.

Insofar as Plaintiffs' Motion seeks to preclude Dr. Yousem from offering his opinion that Z.H.'s MRIs are consistent with findings in children not exposed to Depakote who suffered the same injuries caused by hypoxic-ischemic events, the Court denies Plaintiffs' Motion. Dr. Yousem's experience in reading scans of such children allows him to compare, based on his experience, the scans to those of Z.H. and opine they are consistent. Such an opinion does not require that Dr. Yousem have experience with scans of children who were exposed to Depakote in utero. Nor is Dr. Yousem precluded from testifying that Z.H.'s injuries are inconsistent with the literature and scans of Depakote exposed children he personally reviewed. This is within the realm of his experience based on the materials he personally reviewed.

IT IS SO ORDERED.

s/ Christopher A. Boyko
CHRISTOPHER A. BOYKO
United States District Judge

Dated: December 19, 2016